

5% carbon dioxide/air medical gas mixture.

Essential safety information.



5% carbon dioxide/air medical gas mixture SPC

1. Name of the medicinal product 5% carbon dioxide/air medical gas mixture.

2. Qualitative and quantitative composition 5% carbon dioxide/air medical gas mixture is supplied in high pressure gas cylinders. The air and the carbon dioxide comply with the relevant European Pharmacopoeia Specifications.

The mixture specification is as follows:

carbon dioxide	5% +/-0.5%
air	balance.

3. Pharmaceutical form Medicinal gas, compressed.

4. Clinical particulars

4.1 Therapeutic indications The main use of 5% carbon dioxide/air medical gas mixture is to stimulate respiration after a period of apnoea and in the management of chronic respiratory obstruction after the obstruction has been relieved.

4.2 Posology and method of administration 5% carbon dioxide/air medical gas mixture is administered by inhalation through the lungs usually for a fixed period.

The duration and circumstances of the exposure to 5% carbon dioxide/air medical gas mixture is always at the discretion of the attendant physician who makes the decision in the light of the particular circumstances.

4.3 Contraindications There are no contraindications for the use of 5% carbon dioxide/air medical gas mixture in any age group.

The duration and circumstances of the exposure to 5% carbon dioxide/air medical gas mixture is always at the discretion of the attendant physician who makes the decision in the light of the particular circumstances.

4.4 Special warnings and precautions for use The administration of 5% carbon dioxide/air medical gas mixture to patients with chronic respiratory disease or drug induced respiratory depression is potentially dangerous. It should not be given to acidotic patients.

4.5 Interaction with other medicinal products and other forms of interaction 5% carbon dioxide/air medical gas mixture will interact with anaesthetic agents when the concentration is raised and gives rise to cardiac dysrhythmias. The threshold for dysrhythmias varies with different drugs.

By altering pH, the use of 5% carbon dioxide/air medical gas mixture influences the uptake and distribution of many drugs, including neuromuscular blocking agents and hypotensive agents.

5% carbon dioxide/air medical gas mixture will interact with adrenergic substances such as adrenaline. They should not be used together.

4.6 Pregnancy and lactation 5% carbon dioxide/air medical gas mixture is not contraindicated in pregnancy and is unlikely to influence lactation.

4.7 Effects on ability to drive and use machines The inhalation of 5% carbon dioxide/air medical gas mixture should be directly supervised by a clinician so that the question of driving or controlling machinery should not arise.

4.8 Undesirable effects The use of 5% carbon dioxide/air medical gas mixture may produce sweating, nausea and headache in a small number of patients.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via The Yellow Card System www.mhra.gov.uk/yellowcard

4.9 Overdose No overdose effects are seen with 5% carbon dioxide/air medical gas mixture but its use needs careful supervision.

5. Pharmacological properties

5.1 Pharmacodynamic properties Pharmacotherapeutic Group - medical gas.
ATC code: V03AN.

5% carbon dioxide/air medical gas mixture consists of 5% carbon dioxide with the balance being medical air (or a 21% oxygen /79% nitrogen mixture).

The pharmacological particulars of the constituent gases are as follows:

The characteristics of carbon dioxide are:

- odourless, colourless gas
- molecular weight 44
- sublimation point -78.5°C (at 1bar(g))
- density 1.872kg/m³ (at 15°C).

The effect of inhaling carbon dioxide, or of its accumulation in the body through ventilation defects, varies with the tension achieved in the blood, the duration and condition of the exposure and the susceptibility of the individual concerned.

The characteristics of medical air are:

- odourless, colourless gas
- molecular weight 29
- boiling point -194°C (at 1bar(g))
- density 1.225kg/m³ (at 15°C).

Atmospheric air contains approximately 21% oxygen, 78% nitrogen and 1% argon with trace contents of other inert gases (xenon, neon and krypton).

The nitrogen is absolutely inert, but the oxygen in air is an absolute necessity for life for its cellular respiratory function.

If a normal conscious patient inhales 5% carbon dioxide/air medical gas mixture, the rate and depth of breathing rises and the minute volume increases. The skin becomes warm and pink and there may be sweating and a sense of discomfort. Dizziness may develop and some patients may become unconscious. However, when the subject returns to breathing in air, an "off-effect" is commonly seen with malaise, pallor, headache and occasional nausea and vomiting, probably due to metabolic effect induced by inhaling a volatile acid.

5.2 Pharmacokinetic properties When 5% carbon dioxide/air medical gas mixture is inhaled, absorption from the lungs into the blood is rapid and a new equilibrium between the concentration in alveolar air and that in the blood is soon established. The gas is carried partly in solution in the plasma, but mostly either as bicarbonate or as carbamino compound.

The relative quantities in solution and as bicarbonate regulate the reaction of the blood and buffer any change in pH produced by stronger organic acids. The blood concentration of carbon dioxide is set at a higher level and the excretion of the gas is adjusted to maintain the new equilibrium by increasing output.

5.3 Preclinical safety data None.

6. Pharmaceutical particulars

6.1 List of excipients None.

6.2 Incompatibilities The constituent gases of 5% carbon dioxide/air medical gas mixture are chemically inactive and will not normally react with other compounds at normal temperatures.

6.3 Shelf life 36 months.

6.4 Special precautions for storage 5% carbon dioxide/air medical gas mixture cylinders should be:

- stored under cover, preferably inside, kept dry and clean, and not subjected to extremes of heat or cold and away from stocks of combustible material
- stored separately from industrial and other non-medical cylinders
- stored to maintain separation between full and empty cylinders
- used in strict rotation so that cylinders with the earliest filling date are used first
- stored separately from other medical cylinders within the store.

Warning notices prohibiting smoking and naked lights must be posted clearly in the cylinder storage area and the emergency services should be advised of the location of the cylinder store.

Care is needed when handling and using 5% carbon dioxide/air medical gas mixture cylinders.

6.5 Nature and contents of container

Cylinder and valve details 5% carbon dioxide/air medical gas mixture is supplied in high pressure cylinders filled to 137bar(g). Conventional high pressure cylinder valves with side outlets that conform to BS 341 (5/8" BSP F), are fitted to all 5% carbon dioxide/air medical gas mixture cylinders. These cylinders are designed to be used with a pressure regulator.

A summary of 5% carbon dioxide/air medical gas mixture cylinders, their size and construction and type of valve fitted are detailed below:

Cylinder size	Gas content (litres)	Cylinder construction	Cylinder pressure bar(g)
AV	1,350	Aluminium	137
L	6,750	Steel	137

The basic specification for the cylinder valves used in 5% carbon dioxide/air medical gas mixture cylinders is:

Valve component	Specification
Valve body	High tensile brass
Spindle	Steel
Spindle tip	Nylon 6.6
Valve outlet	5/8" BSP (F) side outlet
Valve operation	Handwheel

6.6 Special precautions for disposal and other handling All personnel handling 5% carbon dioxide/air medical gas mixture cylinders should have adequate knowledge of:

- properties of the gas
- correct operating procedures for the cylinder
- precautions and actions to be taken in the event of an emergency.

Preparation for use To prepare the cylinder for use:

- remove the tamper evident seal and the valve outlet protection cap. Ensure cap, where fitted, is retained so that it can be refitted after use
- do not remove and discard any batch labels fitted to the cylinder
- ensure that an appropriate regulator is selected for connection to the cylinder
- ensure the connecting face on the regulator is clean and the sealing washer fitted is in good condition
- ensure that the cylinder valves and any associated equipment are not lubricated and kept free from oil and grease
- connect the regulator, using moderate force only and connect the tubing to the regulator/flowmeter outlet. Only the appropriate regulator should be used for the particular gas concerned
- open the cylinder valve slowly and check for any leaks.

Leaks Having connected the regulator or manifold yoke to the cylinder, check the connections for leaks using the following procedure:

- should leaks occur this will usually be evident by a hissing noise
- should a leak occur between the valve outlet and the regulator or manifold yoke, depressurise and remove the fitting and fit an approved sealing washer. Reconnect the fitting to the valve with moderate force only, fitting a replacement regulator or manifold tailpipe as required
- sealing or jointing compounds must never be used to cure a leak
- if leak persists, label cylinder and return to BOC.

Use of cylinders When 5% carbon dioxide/air medical gas mixture cylinders are in use, ensure that they are:

- only used for medicinal purposes
- turned off, when not in use, using only moderate force to close the valve
- only moved with the appropriate size and type of trolley or handling device
- handled with care and not knocked violently or allowed to fall
- firmly secured to a suitable cylinder support when in use
- not allowed to have any markings, labels or batch labels obscured or removed
- not used in the vicinity of persons smoking or near naked lights.

After use When the 5% carbon dioxide/air medical gas mixture cylinders are empty, ensure that the:

- cylinder valves are closed using moderate force only and the pressure in the regulator or tailpipe released
- valve outlet cap, where fitted, is replaced
- empty cylinders are immediately returned to an empty cylinder storage area for return to BOC.

7. Marketing authorisation holder BOC Ltd, The Priestley Centre, 10 Priestley Road, The Surrey Research Park, Guildford, Surrey GU2 7XY.

8. Marketing authorisation number(s) PL 0735/5014R.

9. Date of first authorisation/renewal of the authorisation Date first granted: 24/01/1991.
Date of renewal: 02/10/1998.

10. Date of revision of the text 25/05/2016

11. Dosimetry (if applicable) Not applicable.

12. Instructions for preparation of radiopharmaceuticals (if applicable) Not applicable.

Additional Safety Information

1. Contact information BOC telephone number to be used in the event of an emergency
UK 0800 111 333

2. Hazards Classification labelling and packaging regulations



Warning.
Contains gas under pressure; may explode if heated (H280).
Protect from sunlight: store in a well-ventilated place (P410 + P403).

Dangerous Preparations Directive



Keep out of the reach of children (S2).

Label statements

- No smoking or naked flames near medical gas cylinders.
- Use no oil or grease.
- Keep away from extremes of heat and combustible material.
- Store cylinders under cover in a clean, dry and well ventilated area.

5% carbon dioxide/air medical gas mixture is supplied as a compressed gas in a high pressure cylinder.

Cylinders may explode if subjected to extremely high temperatures (if involved in a fire).

The UK exposure limit for carbon dioxide (as defined in EH40/2005) specifies:

- the Long Term Exposure Limit (LTTEL), Time Weighted Average (TWA) over 8 hours is 5000ppm
- the Short Term Exposure Limit (STEL) (measured over a 15 minute period) is 15000ppm.

- 3. Fire fighting measures** If 5% carbon dioxide/air medical gas mixture cylinders are involved in a fire:
- if it is safe to move the cylinders,
 - close cylinder valve to stop the flow of product
 - move cylinders away from source of heat
 - if it is not safe to move the cylinders,
 - cool with water from a protected position.

All types of fire extinguishers may be used when dealing with a fire involving 5% carbon dioxide/air medical gas mixture cylinders.

Fire fighters should use self-contained breathing apparatus when dealing with a fire involving 5% carbon dioxide/air medical gas mixture cylinders within a confined space.

There are no hazardous combustion products released from the gas.

- 4. Accidental release measures** If a large volume of 5% carbon dioxide/air medical gas mixture is released, if it is safe to do so, you should:
- close cylinder valve
 - where possible, eliminate all sources of ignition.

If release continues, evacuate the area and ensure that the affected area is adequately ventilated before re-entry.

Self-contained breathing apparatus is required to be used if 5% carbon dioxide/air medical gas mixture is released in a confined area.

- 5. Exposure controls** When using 5% carbon dioxide/air medical gas mixture cylinders, ensure adequate ventilation.

- 6. Disposal considerations** It is recommended that 5% carbon dioxide/air medical gas mixture cylinders should not be vented after use – they should be returned to BOC with any residual gas where they will be vented before refilling in a safe environment.

If, for safety reasons, a cylinder is required to be vented after use, the gas should be vented to atmosphere in a well ventilated area.

Contact BOC if further guidance on venting cylinders is required.

- 7. Transport of cylinders** When 5% carbon dioxide/air medical gas mixture cylinders are required to be transported, ensure that the cylinders are:
- located in a compartment separated from the driver
 - adequately restrained
 - not leaking and have their valves closed.

The vehicle must be adequately ventilated. Ensure the driver is aware of the potential hazards of the load and knows what to do in the event of an accident or an emergency.

It is advisable to provide the driver with written instructions that detail the actions to be taken in the event of an accident or emergency.

Cylinders should be removed from the vehicle as soon as possible.

8. Transport information	UN number	UN1956
	Proper shipping name:	Compressed gas, N.O.S. (carbon dioxide)
	Material:	Class 2
	Labels	2.2
	Hazard identification number	20
	Emergency Action Code	2TE
	Tunnel Restriction Code	E
	Transport category	3

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